REMARKS/ARGUMENTS

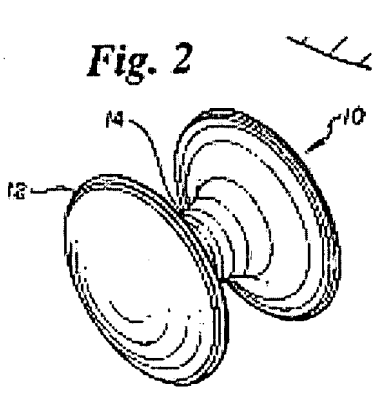
The Office Action mailed June 27, 2007 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims originally in the application were claims 1-35. Claims 2, 3, 7, 8, 9, 10, 22, 23, 24, 26, 27, 28, 29, 30, and 33 have been cancelled. The claims presented for examination are: claims 1, 4-6 11-21, 25, 31, and 34-35.

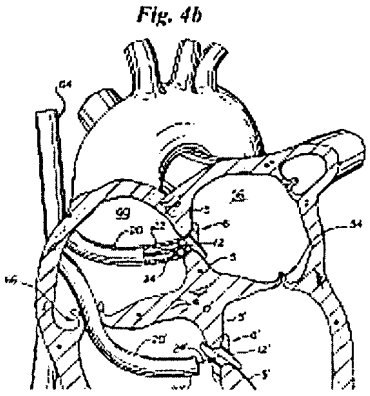
35 U.S.C. §102 Rejection – Linden et al

In the Office Action mailed June 27, 2007 on page 2, claims 1, 4, 7, 8, 11, 16-21, 31, 32, 34, and 35 were rejected under 35 U.S.C. §102(b) as being anticipated by the Linden et al reference (US Patent No. 5,634,936). Applicants have amended the claims and believe the invention claimed in the amended claims is not anticipated by the Linden et al reference. The standard for a 35 U.S.C. §102 rejection is stated in RCA Corp. v. Applied Digital Systems, Inc, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention."

The Linden et al Reference

The Linden et al reference is United States Patent No. 5,634,936 which states: "The present invention relates generally to the closure of intravascular defects and more specifically to a device for closing a cardiovascular or cardiac septal defect, the device being made of a polymeric material delivered to the site of the defect by a catheter and hardened in-situ to a predetermined configuration to function as a plug." The Linden et al reference is illustrated by FIGS. 2 and 4B reproduced below and described in the Linden et al specification as quoted below.





"As shown in FIG. 2, a device of the invention shown generally at 10 in one embodiment, is a preshaped plug 12 in the form of a disc with a narrower center portion 14. In this form, the device 10 serves as a plug 12 which is inserted into a tissue defect such as a septal defect. The polymeric material in this embodiment is ideally a polymeric self-hardening foam or sponge material which is soft and easily deformable so that it can be readily plugged into the defect. ... The plug 12 is made of a polymeric material in a specific conformation which reacts with a hardening agent after being installed in the septal defect to change the modulus of the material but not the preformed shape. As the material hardens, its modulus increases. .... The polymeric material may be a polyurethane foam formed from the mixture of isocyanates and polyols. Polyurethane foams are formed form the reactions of isocyanates and acids. As an example of such methylene diisocyanate reaction with polyvinyl acetic acid copolymerized with polyethylene oxide would cause the formation of a crosslinked polymer and the release of carbon dioxide, which would form the foaming agent..... In its deliverable form, plug 12 would preferably be bathed or presoaked in an organic solution or aqueous solution of a specific pH or ionic concentration. This is because the mechanism of hardening in this case resides with the transition or replacement of one fluid for another. For instance, a solution of water and DMSO (dimethylsulfoxide) at a specific pH would keep the polymer soft and contracted. Once the fluid is replaced by a second fluid at a different pH probably near physiological pH, or in contact with blood, the polymer expands and hardens."

"In FIG. 4b, plug 12 is shown being placed in ASD 6. Plug 12' is shown already in place in VSD 6' with catheter 20' in the process of being withdrawn. Plug 12 is delivered to the area of septal defect 6 by catheter 20 and inserted in place, centered in septal defect 6 as shown in FIG. 4b. Plug 12 may be either pulled or pushed out of catheter 20. Upon expulsion from its delivery system, plug 12 will assume its preformed shape in a narrow center portion with enlarged ends. Plug 12' is shown in place closing off ventricular septal defect 6', as corkscrew holder 24' and catheter delivery means 20' are being withdrawn."

"After its placement in the area of defect 6, plug 12 is hardened in-situ. The polymeric material may be hardened by alterations in pH effected by infusion through catheter 20 of a solution of pH differing from the pH of the original solution.

Alternatively, the material may be hardened by the addition of an organic solvent or through dilution. Hardening may also be effected by permeation into the pores of the polymeric material of a secondary material delivered by the catheter that would precipitate with a change in pH or by the addition of a secondary material in gel form or solution."

The Linden et al reference discloses a "polymeric self-hardening foam or sponge material which is soft and easily deformable so that it can be readily plugged into the defect. ... which reacts with a hardening agent after being installed."

In contrast Applicants claimed invention includes a "shape memory polymer (SMP) foam .... having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall, ... having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, ... having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall."

Applicants point out that the following elements of Applicants' amended claims 1, 4, 7, 8, 11, 16-21, 31, 32, 34, and 35 are not found in the Linden et al reference:

> a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}, said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall, said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature

above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall,

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall,

wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly,

providing a closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}, said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall,

transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.

Since the elements described above are not found in the Linden et al reference, the Linden et al reference does not support a 35 U.S.C. §102(b) rejection of Applicants' amended claims 1, 4, 7, 8, 11, 16-21, 31, 32, 34, and 35 and the rejection should be withdrawn.

35 U.S.C. §103 Rejection – Linden in View of Michlitsch and Langer

In the Office Action mailed June 27, 2007 on pages 3 and 4, claims 1, 4-21, 25, 31, 34, and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Linden et al reference (US Patent No. 5,634,936) in view of the Michlitsch reference (US 2006/0155330) and Langer et al reference (US 6,388,043). Applicants have amended the claims and believe the invention claimed in the amended claims is patentable over the Linden et al and Michlitsch and Langer et al references.

***Prima Facie* Case of Obviousness Has Not Been Established**

The rejection of claims 1, 4-21, 25, 31, 34, and 35 under 35 U.S.C. §103(a) is respectfully traversed. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. The Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). There must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in Graham v. John Deere Co. is

used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

References Do Not Teach All Claim Limitations

The criteria that prior art reference (or reference when combined) must teach or suggest all the claim limitations have not been met. The Linden et al reference, the Michlitsch reference, and Langer et al reference do not disclose many Applicants' claim limitations. In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in Graham v. John Deere Co. is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art" and ascertaining "the differences between the prior art and the claims at issue." The Linden et al reference, the Michlitsch reference, and Langer et al reference do not disclose the limitations of Applicants' claims 1, 4-21, 25, 31, 34, and 35 identified below.

> a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}, said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall, said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall,
>
> a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a

volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall,

wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly,

providing a closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}, said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall,

transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.

Since the limitations listed and described above are not shown by the Linden et al reference, the Michlitsch reference, or Langer et al reference, a *prima facie* case of obviousness has not been established. Further, since the Linden et al reference, the Michlitsch reference, and Langer et al reference fail to show the

claim limitations of Applicants' claims 1, 4-21, 25, 31, 34, and 35 there can be no combination of the three references that would show Applicant's invention. There is no combination of the Linden et al reference, the Michlitsch reference, and Langer et al reference that would produce the combination of elements of Applicants' claims 1, 4-21, 25, 31, 34, and 35. Thus, the combination of references in the Office Action mailed June 27, 2007 fails to support a rejection of claims 1, 4-21, 25, 31, 34, and 35 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

No Reasons for Combining Linden, Michlitsch, and Langer References

The criteria that the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.) has not been established. The rejection in the Office Action mailed June 27, 2007 does not provide an explanation of how or why the Linden et al reference, the Michlitsch reference, and Langer et al reference would be combined.

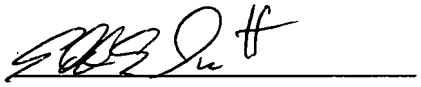
The Linden et al reference, the Michlitsch reference, and Langer et al reference do not recognizes the problem solved by Applicant's claimed invention. The Linden et al reference, the Michlitsch reference, and Langer et al reference fail to disclose the benefits of Applicants claimed invention provided by "providing a closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}, said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall, compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a

temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly." Thus, the combination of references in the Office Action mailed June 27, 2007 fails to support a rejection of claims 1, 4-21, 25, 31, 34, and 35 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated June 27, 2007 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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Dated: September 21, 2007